DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 22, 2014

Albaad, Ltd.
% Robert J. Staab
Official Correspondent
Regulatory and Technical Associates
30 Neck Road
Old Lyme, CT 06371

Re: K140077
Trade/Device Name: Albaad Plastic Applicator Tampons Unscented
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: August 20, 2014
Received: August 21, 2014

Dear Robert J. Staab,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _K140077

Device Name: **ALBAAD Plastic Applicator Tampons** (Various Trade Tampons Sold Under Private Labels As *Plastic Applicators)*

Indications for Use:

The Albaad Plastic Applicator Tampons, Available in regularand super absorbency are inserted into the vagina and used to absorb menstrual or other vaginal discharge.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

Device Name: Albaad Plastic Applicator Tampons

Name Address Telephone number of submitter, contact person dated 9/11/14
Robert J Staab, Ph.D. for Albaad as Official Correspondent
RTA, Inc., 30 Neck Road, Old Lyme CT 06371
860 434 5872
Manufacturer
Albaad Fem Israel
Tampons Division of Albaad Massoud Itzhak Ltd
Caesarea Industrial Park 38900
POB B 3541
Israel

The registration number is 9613295

Regulation number, Regulation name, Classification, product code for Albaad tampons
OBGYN Panel, Unscented Menstrual Tampons, 21 CFR 884 5470, PRODUCT CODE HEB

Predicate Device: Rostam Plastic Applicator Tampons K042773

Indications for Use:
The Albaad Plastic Applicator Tampons available in regular and super absorbency are inserted into the vagina and used to absorb menstrual or other vaginal discharge.

Device description:
The Albaad Tampons are unscented Plastic Applicator tampons.

The Applicator Tampons are inserted into the vagina to absorb menstrual or other vaginal discharge.

These tampons applicator types, will be marketed in 2 absorbencies: regular (6-9g) and super, (9-12g)

These Tampons are made from 100% viscose, and a 100% cotton cord. The applicators are low density and high density polyethylene.

The materials used in these tampons are similar to those used in other legally marketed tampons.

Technological Characteristics
To compare the Predicate Device:

- The pledget/wadding material has not been dramatically changed; it is viscose
- The withdrawal cord was not changed, it is 100% cotton.
- The applicators design was slightly changed and the material is polyethylene, similar to the predicated device.

There are differences between the subject device and predicate device: (1) the difference in the pledget designs; (2) the lack of overwrap on the pledget in the subject device; it has been shown to be unnecessary; and (3) the difference in the attachment of the withdrawal cord to the pledget; the withdrawal cord is threaded through the crossed pattern pledget for adherence as opposed to sewing within the pledget.

These differences are similar to currently marketed products. The nonclinical testing program was carried out for the G3 tampon which included the differences noted above. This test program showed a lack of toxicity, lack of impact on vaginal microflora and TSST-1 production. The results observed were similar to historical results seen for the predicate device.

Assessment of Performance Standards: Not Applicable

Non-Clinical Testing: Biocompatibility testing and safety evaluations of tampon components were carried out for acute systemic toxicity,, vaginal irritation, sensitization and cytotoxicity as well as impact to vaginal microflora and toxic shock syndrome toxin 1.

The biocompatibility tests were conducted in accordance with ISO 10993-5:2009 (cytotoxicity), ISO 10993-10:2010 (sensitization and vaginal irritation), and ISO 10993-11:2006 (acute systemic toxicity).

Standard Syngina testing confirmed the absorbency of these Tampons

Clinical testing: N/A.

Conclusions
The results of these tests demonstrate that these Tampons are equivalent in terms of safety and effectiveness to the predicate device. The review of existing toxicological data in the public literature, also confirms the safety of these standard tampons.